

### **REMARKS**

#### **Status of the claims**

With entry of the current amendment, claims 1-20 and 27-34 have been cancelled and new claim 35 has been added. Accordingly, claims 21-26 and 35 are pending in the application.

The amendments to the specification and claims add no new matter.

The amendments to the specification update the priority information and provide federal funding information.

New claim 35 recites an immune deficient mouse that is a SCID mouse. Support for the new claim can be found throughout the specification, *e.g.*, on page 6, lines 30-31.

The objection/rejections will be addressed in the order presented in the July 1, 2004 Office Action.

#### **Priority information**

The first paragraph of the specification has been updated as required and also revised to indicate that the instant application is a continuation application, not a divisional application.

#### **Oath/Declaration**

The Examiner has required a new oath or declaration because the Declaration on file incorrectly designates 08/732,676 as a provisional application. A substitute Declaration is submitted herewith. It designates Application U.S. Ser. No. 08/732,676 as a non-provisional Application.

One of the inventors, Karen Klein, has not signed the substitute Declaration. Therefore, a petition under 37 C.F.R. § 1.183 to waive the requirements of 37 C.F.R. § 1.67, including proof of the pertinent facts, the fee set forth in § 1.17(h) and the last known address of the non-signing inventor accompanies this response. The petition explains that Applicants exercised diligence in attempting to obtain Dr. Klein's signature.

### **Claim objections**

Claims 22-26 were objected to because the claim dependency was incorrectly numbered in view of the re-numbering of the claims. Applicants have amended the claims to provide proper dependency.

### **Obviousness-type double patenting**

Claims 21-26 were rejected for alleged obviousness-type double patenting over claims 5-10 of U.S. Patent No. 6,107,540.

Claims 21-26 were also rejected for alleged obviousness-type double patenting over claims 10-17 of U.S. Patent No. 6,365,797.

Claims 21-26 were provisionally rejected for alleged obviousness-type double patenting over claims 21-26 of co-pending Application No. 10/062,925.

Claims 21-26 were further provisionally rejected for alleged obviousness-type double patenting over claims 21-26 and 29 of co-pending Application No. 10/066,266.

U.S. Patent No. 6,107,540, U.S. Patent No. 6,365,797 B1, Application No. 10/062,925, and Application No. 10/066,266 and the subject application are commonly owned by the Regents of the University of California.

Applicants submit terminal disclaimers and a Certificate under 37 C.F.R. § 3.73(b) (attached to the Power of Attorney) with this Amendment. The terminal disclaimers disclaim the terminal portion of the term of a patent granted on the instant application over U.S. Patent No. 6,107,540, U.S. Patent No. 6,365,797, and patents that may grant with the relevant claims of Application No. 10/062,925, and Application No. 10/066,266. Applicants note that the filing of a terminal disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection. See, MPEP §804.02.

In view of the filing of the terminal disclaimers, Applicants respectfully request withdrawal of the obviousness-type double patenting rejections.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claim 21 was rejected as allegedly confusing regarding the antecedent basis of "the" in b) and c). The Examiner contends that the body of the claim should not refer back to the preamble. Applicants respectfully traverse. The Examiner appear to be referring to the "the" preceding "composition" in steps b) and c). Applicants are aware of no prohibition about the claim referring back to the preamble. MPEP § 2173.05(e) merely indicates that a lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. This passage provides no suggestion that the earlier recitation or limitation cannot be in the preamble. Applicants respectfully request that the Examiner provide an authority for this assertion.

Claim 22 was rejected as lacking antecedent basis in that there is no "detecting" in claim 21. Claim 22 has been amended to recite "determining". Applicants believe that this addresses the rejection.

Claims 23-25 were rejected as allegedly confusing as to what is being further limited. Although Applicants disagree, in order to expedite prosecution, the claims have been amended.

Claim 26 was rejected as allegedly confusing as to what "respectively" refers to and as allegedly confusing as to whether step (b) limits the composition in claim 21 or is an additional step. Although Applicants disagree, in order to expedite prosecution, the claims have been amended.

In view of the foregoing, Applicants respectfully request withdrawal of the rejections.

**Rejections under 35 USC § 102**

Claims 21-23, and 26 are rejected as allegedly anticipated by Soff *et al.* (*J. Clin. Invest.* 96:2593-2600, 1995). Applicants respectfully traverse the rejection, and herein provide evidence in the form of a declaration and evidence under 37 C.F.R. § 1.131 that the claimed subject matter was invented prior to the publication date of the cited reference. The declaration

explains that prior to December 1995, the inventors submitted an Invention Report to their employer. The Invention Report showed that the inventors developed *in vivo* prostate cancer models using immunodeficient SCID mice. Two xenografts were established that could be serially transplanted. These xenografts retained the clinical feature of prostate cancer. The invention disclosure indicates that the models could be used as a tool to screen potential prostate cancer drugs. Thus, the declaration and accompanying evidence unequivocally establish that the claimed invention was conceived of and reduced to practice by all of the inventors prior to December 1995, the publication date of Soff *et al.*

Applicants respectfully request that in accordance with MPEP § 715.04(I), the Declaration be deemed sufficient in the absence of the signature of one of the co-inventors, Dr. Klein. As explained above, Applicant's agents have attempted to reach Dr. Klein on numerous occasions at her last known address (*see*, the accompanying petition under 37 C.F.R. § 1.183) to obtain her signature on the substitute Declaration for this application and related applications. These attempts have been unsuccessful. Further, Applicants have also attempted to obtain her signature on the Declaration submitted under 37 C.F.R. § 1.131. The delivery to her home address was sent via FedEx (see Appendix 1, attached hereto) on November 22, 2004. In view of Applicant's diligent, but unsuccessful, efforts to obtain Dr. Klein signatures on the substitute Declaration and the Rule 1.131 Declaration, Applicants respectfully request that the Rule 1.131 Declaration be deemed sufficient in the absence of Dr. Klein's signature.

In summary, Applicants have provided a declaration pursuant to 37 C.F.R. § 1.131 and proper evidence that the claimed invention was conceived and reduced to practice by all of the inventors prior to December 1995. Accordingly, Applicants respectfully request withdrawal of the rejection.

### **Rejections under 35 U.S.C. §103**

Claims 21, 24, and 25 are rejected as allegedly unpatentable over Soff *et al.* taken with Soos *et al.* or Stephenson *et al.*

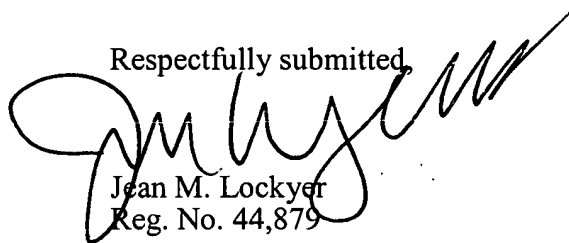
Applicants have provide a Rule 1.131 Declaration by the inventors to antedate the Soff, *et al.* reference. Accordingly, Soff *et al.* is not available as prior art. Applicants therefore respectfully request withdrawal of the rejection.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Jean M. Lockyer  
Reg. No. 44,879

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November 22, 2004

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Re: US Patent Application No. 10/022,115  
filed December 14, 2001  
for MICE MODELS OF HUMAN PROSTATE CANCER PROGRESSION  
Inventors: Charles L. Sawyers *et al.*  
UC Case No. 96-540-4  
Our file No. 02307K-1413-12US

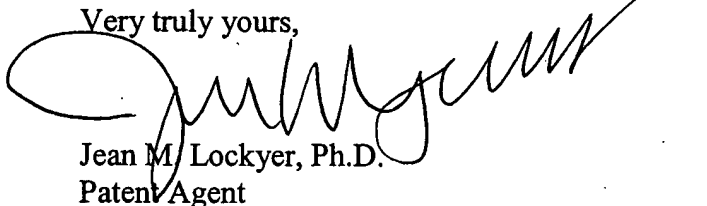
Dear Doctors:

We recently received an Office Action for the above patent application. A December 1995 reference by Soff *et al.* (*J. Clin. Invest.* 96:2593-2600) was cited by the Examiner as alleged prior art. This paper was published within a year before the filing date of our priority application. Therefore, we can file a statement attesting to the fact that our date of invention was before the publication date of Soff *et al.* I have prepared such a statement (1.131 Declaration). I need each of your signatures; they need not be all on the same copy of the 1.131 Declaration.

Please sign the Declaration and return it to me as soon as possible.

Please let me know if you have any questions or comments.

Very truly yours,



Jean M. Lockyer, Ph.D.  
Patent Agent

JML/mcd  
Enclosure  
60362551 v1

From: Origin ID: (415)576-0200  
Malinda Dagit  
Townsend and Townsend and Crew LLP  
Two Embarcadero Center  
8th Floor  
San Francisco, CA 94111



Ship Date: 22NOV04  
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Account#: S \*\*\*\*\*

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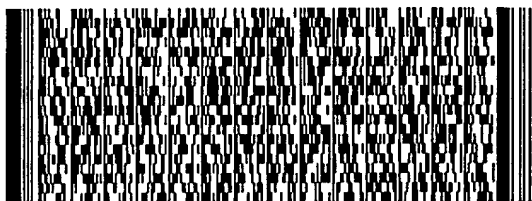
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BILL SENDER

Karen Klein

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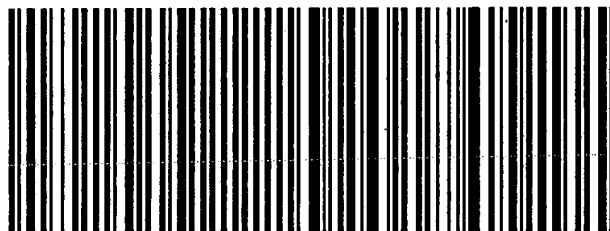
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<b>Delivery date</b>	Nov 23, 2004 10:15 AM	<b>Delivery location</b>	Los Angeles, CA
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6:38 AM	At local FedEx facility	MARINA DEL REY, CA	
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